

In re Application of:
Serial No.:
Atty. Docket No.:

Brown
09/899,432
511-051

Art Group:
Examiner:

1617
Jiang, Shaojia A.

REMARKS

Claim Status

Claims 2-3, 5-6, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87 and 89-90 were rejected. These claims have been amended.

Claim Rejections - 35 U.S.C. § 112

The examiner rejects claims 5-6, 17-18, 23-24, 29-30, 35-36 and 89-90 because the examiner feels that the term "relative proportions" is indefinite. These claims have been amended above to clarify that the relative proportions of the constituent alcohols are proportions by weight relative to the total weight of the alcohols. This was obviously implied by the language of these claims, wherein the total percentages approached 100% (thereby implying that it was the total weight of the alcohols and not the total weight of the composition). Accordingly, in light of the above amendment to the claims, the applicant respectfully requests that the examiner withdraw the instant rejection.

Claim Rejections - 35 U.S.C. § 103

The examiner has rejected claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87 and 89-90 as being obvious over Katz (5,952,392) in view of Arquette (WO 9920224) and Katz (4,874,794) and Katz (5,070,107) for the reasons of record stated in the office action dated May 20, 2003.

The examiner points out that Katz '392 discloses long chain fatty acids, including oleic acid) in combination with monounsaturated long chain alcohols. The examiner feels that Arquette (WO 9920224) discloses a pharmaceutical composition comprising the instant fatty alcohols, jojoba oil, and fatty acid esters, with a physiologically compatible carrier for topical applications. The examiner points to the abstract and page 3, lines 15-22. However, a reading of the abstract clearly discloses an "emollient" composition and not a "pharmaceutical composition". Further, examination of page 3, lines 15-22 shows the carrier of the present invention, but definitely does not teach or

suggest that this carrier has pharmaceutical properties. At best, this publication teaches that the fatty alcohol, fatty ester combination makes an effective carrier, but not one that is physiologically active. Therefore, Katz '392 and Arquette (WO 9920224), either individually or in combination, do not teach or disclose the surprising and unexpected result of physiological activity of the present invention.

The examiner also feels that Katz '794 discloses the effective amounts of long chain fatty alcohols, in combination with a physiological compatible carrier, are 0.1 to 25 percent by weight and that Katz '107 discloses that the effective amounts of long chain fatty alcohols broadly, with a physiologically compatible carrier are 0.1 mg to 2/ 50kg of body weight. However, the examiner appears to ignore the fact that Katz "392, '794 and '109 discloses effective amounts for fully saturated long chain fatty alcohols and not the effective amounts of monounsaturated long chain fatty alcohols according to the present invention.

With respect to the chemical arts, it is well established that to the effect a patent application discloses ranges that overlap or lie inside ranges disclosed by the prior art, the invention may be patentable if the applicant can show criticality in the claimed range by evidence of unexpected results. Application of Wertheim, 541 F.2d 257, 267 (C.C.P.A. 1976); see also, In re Malagari, 499 F.2d 1297, 182 USPQ 549 (Cust. & Pat. App. 1974); In re Orfeo, 440 F.2d 439, 169 USPQ 487 (1971).

The claims in the present invention, which are drawn to monounsaturated long chain alcohols and not saturated long chain alcohols, have been amended to include the limitation that these alcohols are mixed with polar hydrophilic salts that, when mixed, produce the unexpected result of efficacy that is approximately 50 time greater than that of the alcohol alone. There is no teaching or suggestion in the prior art that a mixture of long chain monounsaturated alcohols mixed with polar hydrophilic salts would produce an antiviral effect, let alone one that is approximately 50 times greater than that of the alcohol alone. Support for this mixture may be found on page 14 of the specification. Additional proof of the efficacy, in the form of a table comparing the cytotoxicity of three compositions, is attached. In table 2, TRA01-024 is n-dococenol and TRA01-025 is the

composition of monounsaturated alcohols mixed with polar hydrophilic salts according to the present invention. As can be seen from Table 2 the cytotoxicity of n-dococenol is >25% while, unexpectedly and surprisingly, the cytotoxicity of the mixture according to the present invention is 0.356%, approximately 50 times more effective.

The claimed range of monounsaturated alcohols falls within the broad range disclosed in Katz et al. It is respectfully submitted, however, that Katz et al. do not anticipate the claimed invention since they do not place Applicants' claimed invention, using monounsaturated alcohols mixed with polar hydrophilic salts in a physiologically active carrier, in the possession of the public.

Katz et al., state that totally saturated long-chain alcohols are applied using a physiologically compatible carrier. However, there is no teaching or suggestion within any of the Katz et al. references that there would be unexpected and surprising benefits by using the addition of polar hydrophilic salts, particularly the salts of the present invention.

Further, Katz et al. do not provide any teachings regarding antiviral treatment, with respect to effective dosing levels, dosing schedules, manner of administration, for compositions comprising monounsaturated long chain alcohols mixed with polar hydrophilic salts in a physiologically active carrier. Instead, Katz's examples relate solely to fully saturated long chain alcohols. Katz et al. never attempts to broaden the applicability of their results to monounsaturated long chain alcohols or monounsaturated long chain alcohols mixed with polar hydrophilic salts in a physiologically active carrier. However, those skilled in the art would appreciate that results achieved with fully saturated long chain alcohols in a merely physiologically compatible carrier cannot be freely imputed to monounsaturated long chain alcohols mixed with polar hydrophilic salts in a physiologically active carrier, let alone one having an efficacy approximately 50 times greater than that of the alcohols alone.

Applicant's claimed compositions, as now amended, therefore provide persons with viral activity superior, or at least alternative, composition having antiviral activity of both the long chain alcohols synergistically combined with that of polar hydrophilic salts according to the present invention. Persons skilled in the art could not ascertain such a

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composition using the teachings of Katz et al., since Katz et al. were clearly not in possession of such teachings.

For the above-stated reasons, Katz et al. do not place the subject matter of applicant's claims in the possession of the public. The Katz et al. reference therefore, either individually or in combination with Arquette et al., do not anticipate the claimed invention.

For the above, the applicant respectfully requests that the examiner withdraw the instant rejection and allow the claims, as now amended.

Respectfully submitted,

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